K073556

JUN 24 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

Date of Application: November 21, 2007

APPLICANT: MedXpert GmbH
Poststr. 55
D-79423 Heitersheim
Germany
Phone: +49 (7634) 506886
Fax: +49 (7634) 506887
Email: info@medxpert.com

1. Device Name

Trade Name: MedXpert P.E.S. (Pectus Excavatum System)
MedXpert STRATOS™

Common Name: Pectus Excavatum System

2. Classification

Our implant system can be classified according following device names and product codes:

Device:	MedXpert STRATOS™ MedXpert P.E.S. (Pectus Excavatum System)
Medical Specialty:	Part 878, General & Plastic Surgery
Product Code:	HRS
Regulation Number:	888.3030
Device Class:	2

3. Substantial Equivalence

MedXpert's P.E.S & STRATOS™ implant systems are substantial equivalent to the Lorenz Pectus Support Bar (K972420), Lorenz Pectus Support Bar Stabilizer (K981789) and Lorenz Pectus Support Bar System (K061384) of Walter Lorenz Surgical, Inc., Acute Bone Screw (K061206) of Acute Innovations LLC, and MacroPore OS Reconstruction System (K024169) of MacroPore Biosurgery, Inc.

4. Description of the Device

MedXpert's P.E.S. implant system is consisting out of straight bars which can be bended according to the individual anatomic needs of the patient and different stabilizer which can be attached to the bar and secured by the BarLock™ Pin.

MedXpert's STRATOS™ implant system is consisting out of Bar and Rip Clips; Rip Clips are combined by press fit with the bar and with the rips.

5. Intended Use

MedXpert's P.E.S. implant system is intended for use in surgical procedures to repair Pectus Excavatum and other sternal deformities.

MedXpert's STRATOS™ implant system is intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and reconstructions of chest wall and sternum.

6. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that MedXpert's P.E.S & STRATOS™ implant systems are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MedXpert GmbH
% Medagent GmbH & Co. KG
Mr. Franz Menean
Griesweg 47
Muhlheim, Baden-Wurttemberg
Germany 78570

JUN 24 2008

Re: K073556
Trade/Device Name: MedXpert P.E.S. (Pectus Excavatum System), MedXpert STRATOS
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: May 30, 2008
Received: June 11, 2008

Dear Mr. Menean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073556 (pg 1/1)

Indications for Use

510(k) Number: **K073556**

Device Name:
MedXpert P.E.S. (Pectus Excavatum System) Implant System
MedXpert STRATOS™ Implant System

Indications for Use:

MedXpert's P.E.S. implant system is intended for use in surgical procedures to repair Pectus Excavatum and other sternal deformities.
MedXpert's STRATOS™ implant system is intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and reconstructions of chest wall and sternum.

Prescription Use __YES___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bue MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073556